

**Exhibits 1 – 2**

**TO THE DECLARATION OF  
JEFFREY B. COOPERSMITH RE:  
DEFENDANT RAMESH BALWANI'S  
MOTION TO STRIKE IMPROPER  
EXPERT TESTIMONY AND OTHER  
PROHIBITED TESTIMONY**

# **Exhibit 1**

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA, )  
 ) CR-18-00258-EJD  
 PLAINTIFF, )  
 ) SAN JOSE, CALIFORNIA  
 VS. )  
 ) MARCH 22, 2022  
 RAMESH "SUNNY" BALWANI, )  
 ) VOLUME 8  
 DEFENDANT. )  
 ) PAGES 985 - 1154

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TRANSCRIPT OF TRIAL PROCEEDINGS  
BEFORE THE HONORABLE EDWARD J. DAVILA  
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF: UNITED STATES ATTORNEY'S OFFICE  
BY: JOHN C. BOSTIC  
JEFFREY B. SCHENK  
150 ALMADEN BOULEVARD, SUITE 900  
SAN JOSE, CALIFORNIA 95113  
  
BY: ROBERT S. LEACH  
KELLY VOLKAR  
1301 CLAY STREET, SUITE 340S  
OAKLAND, CALIFORNIA 94612

(APPEARANCES CONTINUED ON THE NEXT PAGE.)

OFFICIAL COURT REPORTER:  
IRENE L. RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY  
TRANSCRIPT PRODUCED WITH COMPUTER

02:05PM 1 TEST, WHICH IS ONLY -- IS ONE SPECIFIC TYPE OF CHEMISTRY. IT  
02:05PM 2 DIDN'T HAVE THE CAPABILITIES TO RUN GENERAL CHEMISTRY,  
02:06PM 3 MICROBIOLOGY, CYTOMETRY TESTS.

02:06PM 4 SO THE REASON WHY THERANOS ONLY RAN THAT SMALL SUBSET IS  
02:06PM 5 BECAUSE THAT'S ALL THEY HAD THE CAPACITY TO RUN WAS BASICALLY  
02:06PM 6 ELISA TYPE TESTS.

02:06PM 7 MR. COOPERSMITH: YOUR HONOR, I'M GOING TO OBJECT  
02:06PM 8 AGAIN UNDER 702. THIS WITNESS DOESN'T HAVE THAT KNOWLEDGE TO  
02:06PM 9 OPINE ABOUT WHAT THE DEVICE WAS CAPABLE OF OR WHAT ITS CAPACITY  
02:06PM 10 WAS.

02:06PM 11 MR. BOSTIC: YOUR HONOR, SHE OPERATED THESE DEVICES  
02:06PM 12 ON A DAILY BASIS. I THINK --

02:06PM 13 THE COURT: THE OBJECTION 702 IS OVERRULED.

02:06PM 14 MR. COOPERSMITH: YOUR HONOR, SHE CAN CERTAINLY SAY  
02:06PM 15 WHAT SHE DID BUT TO GO FURTHER AND OPINE AS TO WHAT THE DEVICE  
02:06PM 16 WAS CAPABLE OF AND WHAT ITS CAPACITY WAS I THINK IS BEYOND THIS  
02:06PM 17 WITNESS'S EXPERTISE.

02:06PM 18 THE COURT: WELL, THE ANSWER, AS I UNDERSTAND IT --  
02:06PM 19 AND, MR. BOSTIC, YOU COULD LAY A FOUNDATION IF YOU WOULD LIKE  
02:06PM 20 TO -- IS BASED ON HER TRAINING AND EXPERIENCE AT THE COMPANY.

02:06PM 21 PERHAPS IF YOU WANT TO ASK HER IF THAT'S WHAT SHE WAS  
02:06PM 22 INSTRUCTED OR TRAINED.

02:06PM 23 BY MR. BOSTIC:

02:06PM 24 Q. MS. CHEUNG, FROM YOUR TRAINING AND EXPERIENCE AT THE  
02:07PM 25 COMPANY, DID YOU HAVE AN UNDERSTANDING AS TO WHAT THE EDISON 3

02:07PM 1 SERIES COULD DO AND WHAT IT COULD NOT DO?

02:07PM 2 A. YES.

02:07PM 3 Q. AND BASED ON YOUR TRAINING AND EXPERIENCE AT THE COMPANY,  
02:07PM 4 WHERE WAS THAT LINE? WHAT COULD THE EDISON 3 SERIES DO AND  
02:07PM 5 WHAT COULD IT NOT DO?

02:07PM 6 MR. COOPERSMITH: YOUR HONOR, SAME OBJECTION. 702.

02:07PM 7 THE COURT: OVERRULED.

02:07PM 8 THE WITNESS: CAN YOU REPEAT THE QUESTION?

02:07PM 9 MR. BOSTIC: SURE.

02:07PM 10 Q. WHAT COULD THE EDISON 3 SERIES DO AND WHAT COULD IT NOT DO  
02:07PM 11 BASED ON YOUR TRAINING AND EXPERIENCE?

02:07PM 12 MR. COOPERSMITH: SAME OBJECTION, YOUR HONOR.

02:07PM 13 THE COURT: OVERRULED.

02:07PM 14 THE WITNESS: THE EDISON 3.0 SERIES COULD DO ELISA'S  
02:07PM 15 AND THAT WAS THE ONLY CAPACITY IT COULD DO WAS THAT TYPE OF  
02:07PM 16 CHEMISTRY AND METHODOLOGY, AND THAT WAS WHAT MY UNDERSTANDING  
02:07PM 17 OF THE TECHNOLOGY BASED ON WORKING FOR THE COMPANY.

02:08PM 18 BY MR. BOSTIC:

02:08PM 19 Q. COULD I ASK YOU TO TURN TO EXHIBIT 3741 IN THE BINDER IN  
02:08PM 20 FRONT OF YOU.

02:08PM 21 DO YOU SEE EXHIBIT 3741?

02:08PM 22 A. YES.

02:08PM 23 Q. AND WHAT IS THAT DOCUMENT IF YOU RECOGNIZE IT?

02:08PM 24 A. THIS IS THE TESTING MENU AT THERANOS.

02:08PM 25 Q. HAD YOU PREVIOUSLY HAD THE OPPORTUNITY TO REVIEW THE FIRST

CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

A handwritten signature in black ink that reads "Irene Rodriguez". The signature is written in a cursive, flowing style with a large, decorative flourish at the end of the last name.

IRENE RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

DATED: MARCH 22, 2022

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA, )  
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TRANSCRIPT PRODUCED WITH COMPUTER

10:05AM 1 A. BECAUSE OUR SYSTEM WASN'T WORKING. WE WEREN'T ABLE TO GET  
10:05AM 2 THE QUALITY CONTROLS TO PASS, THIS IS, AGAIN, SOMETHING THAT WE  
10:06AM 3 KNOW THE CONCENTRATION OF, SO THEY SHOULD BE PASSING.

10:06AM 4 AND BASED ON THE PROMISES THAT WE MADE TO OUR PATIENTS,  
10:06AM 5 AND THE COMMITMENTS THAT WE HAD IN TERMS OF DELIVERING RESULTS  
10:06AM 6 IN A CERTAIN AMOUNT OF TIME, AND IF IT WASN'T GETTING OUT, WE  
10:06AM 7 WEREN'T ABLE TO GET THE PATIENT RESULT OUT IN THE TIMEFRAME  
10:06AM 8 THAT WE PROMISED TO THEM.

10:06AM 9 Q. DID THE QC FAILURES HAVE ANY IMPACT ON THE ACCURACY OR  
10:06AM 10 RELIABILITY OF THE PATIENT TESTS THAT WERE GOING TO BE  
10:06AM 11 PERFORMED ON THIS DAY?

10:06AM 12 MR. COOPERSMITH: YOUR HONOR, OBJECTION. RULE 702.

10:06AM 13 THE COURT: CAN YOU LAY A FOUNDATION.

10:06AM 14 MR. BOSTIC: SURE. LET ME REPHRASE.

10:06AM 15 Q. MS. CHEUNG, YOU MENTIONED THAT THESE PROBLEMS CREATED  
10:06AM 16 ISSUES WITH THERANOS PERFORMING TESTS QUICKLY ENOUGH; IS THAT  
10:07AM 17 RIGHT?

10:07AM 18 A. THAT IS CORRECT.

10:07AM 19 Q. AT THERANOS DID YOU UNDERSTAND WHETHER QC FAILURES ALSO  
10:07AM 20 RELATED NOT JUST TO THE SPEED WITH WHICH TESTS COULD BE  
10:07AM 21 CONDUCTED, BUT ALSO TO THE ACCURACY OF THE RESULTS?

10:07AM 22 A. YES.

10:07AM 23 Q. AND WHAT IS THE RELATIONSHIP, AS YOU UNDERSTOOD IT AT THE  
10:07AM 24 TIME, BETWEEN QUALITY CONTROL TESTING AND TEST ACCURACY?

10:07AM 25 MR. COOPERSMITH: YOUR HONOR, IT'S RULE 702. EVEN



10:07AM 1 IF SHE HAS AN UNDERSTANDING, SHE CAN'T TESTIFY AS AN EXPERT  
10:07AM 2 WITNESS. SO RULE 702.

10:07AM 3 THE COURT: I'M SORRY. DID WE TALK ABOUT THIS AT  
10:07AM 4 PRETRIAL? WE PROBABLY DIDN'T ABOUT SPEAKING OBJECTIONS, AND I  
10:07AM 5 APOLOGIZE WE DIDN'T COVER THAT.

10:07AM 6 BUT IF YOU WANT TO, MR. BOSTIC, IF YOUR QUESTIONS ABOUT  
10:07AM 7 WHAT THIS WITNESS KNOWS AND OTHER WITNESSES KNOW THE BASIS OF  
10:07AM 8 THE KNOWLEDGE, IF SHE WAS TRAINED OR AS TO CERTAIN THINGS OR  
10:08AM 9 WHETHER OR NOT THIS MOVES INTO 702 TERRITORY, IT'S SOMETHING  
10:08AM 10 THAT WE TALKED ABOUT YESTERDAY IN REGARDS TO THE WITNESS'S  
10:08AM 11 BREADTH OF KNOWLEDGE AND THE BASIS FOR IT.

10:08AM 12 MR. BOSTIC: UNDERSTOOD, YOUR HONOR.

10:08AM 13 Q. LET ME ASK A PREFATORY QUESTION.

10:08AM 14 MS. CHEUNG, WHEN YOU WERE AT THERANOS, DID YOU RECEIVE  
10:08AM 15 TRAINING AS TO THE PURPOSE FOR QUALITY CONTROL TESTING?

10:08AM 16 A. YES.

10:08AM 17 Q. AND WHAT WERE YOU TOLD AT THERANOS ABOUT WHY QUALITY  
10:08AM 18 CONTROL TESTING WAS NEEDED?

10:08AM 19 A. SO --

10:08AM 20 MR. COOPERSMITH: OBJECTION. HEARSAY, YOUR HONOR.

10:08AM 21 THE COURT: OVERRULED.

10:08AM 22 THE WITNESS: SO FOR THE QUALITY CONTROL TRAINING  
10:08AM 23 THAT WE RECEIVED, ESSENTIALLY IT WAS, AGAIN, A WAY IN WHICH WE  
10:08AM 24 COULD MEASURE THE PERFORMANCE -- THE QUALITY CONTROL SYSTEM WAS  
10:08AM 25 ESSENTIALLY TO GIVE US AN INDICATION OF HOW WELL OUR SYSTEM WAS

11:08AM 1 PATIENT TESTING COULD PROCEED?

11:08AM 2 A. SO QC TESTING IS REALLY TO CHECK THE PERFORMANCE OF YOUR  
11:09AM 3 SYSTEM.

11:09AM 4 SO IF YOU HAVE A HIGH PERCENTAGE OF FAILURES WITHIN THE  
11:09AM 5 SYSTEM, YOU CAN KIND OF FORECAST OUT THAT THAT PERCENTAGE OF  
11:09AM 6 FAILURES COULD LIKELY OCCUR FOR PATIENT TESTING.

11:09AM 7 SO IF WE HAVE A SAMPLE SIZE OF 300, AND WE'RE GETTING  
11:09AM 8 ONE-FORTH OF THAT FAILURES, LET'S SAY IT'S 400, IT MEANS THAT  
11:09AM 9 100 ARE ESSENTIALLY IN THE TERRITORY OF NOT BEING ACCURATE.

11:09AM 10 SO THE REASON THAT IT'S CONCERNING IS THE FACT THAT IT IS  
11:09AM 11 HAPPENING ACROSS TESTS AND ACROSS MACHINES DESPITE US  
11:09AM 12 CONSISTENTLY CHANGING ALL OF THESE DIFFERENT VARIABLES THAT WE  
11:09AM 13 CAN ANTICIPATE THAT IT'S PROBABLY --

11:09AM 14 MR. COOPERSMITH: YOUR HONOR, IF I COULD JUST  
11:09AM 15 INTERRUPT.

11:09AM 16 SHE'S NOW GIVING THE VERY ANSWER THAT WAS OBJECTIONABLE --  
11:09AM 17 SHE'S GIVING THE SAME ANSWER THAT WAS OBJECTIONABLE, AND IT WAS  
11:09AM 18 NOT REALLY RESPONSIVE TO THE QUESTION, SO I WOULD MOVE TO  
11:10AM 19 STRIKE THE ANSWER THAT SHE JUST GAVE AND RENEW THAT OBJECTION.

11:10AM 20 THE COURT: THE ANSWER SHE GAVE I THINK WAS  
11:10AM 21 APPROPRIATE. YOU OBJECTED TO A POINT.

11:10AM 22 DID YOU WANT TO ASK ADDITIONAL QUESTIONS AT THIS POINT?

11:10AM 23 BY MR. BOSTIC:

11:10AM 24 Q. MS. CHEUNG, IF I COULD JUST INTERPOSE A QUICK QUESTION.

11:10AM 25 THE ANSWER THAT YOU'RE GIVING, IS THAT BASED ON THE

11:10AM 1 TRAINING THAT YOU GOT AT THERANOS?

11:10AM 2 A. YES.

11:10AM 3 MR. BOSTIC: I WOULD JUST ASK THAT THE WITNESS BE  
11:10AM 4 ALLOWED TO COMPLETE HER ANSWER.

11:10AM 5 THE WITNESS: OKAY.

11:10AM 6 THE COURT: AND YOU MAY. THE OBJECTION IS OVERRULED  
11:10AM 7 AS TO THAT.

11:10AM 8 THE WITNESS: OKAY. SO THAT'S, THAT'S WHY IT WAS  
11:10AM 9 CONCERNING. IT WAS CONCERNING BECAUSE IF YOU JUST EXTRAPOLATE  
11:10AM 10 OUT ESSENTIALLY THE PERCENTAGE OF FAILURES THAT ARE HAPPENING  
11:10AM 11 ACROSS THE SYSTEM, EVEN IF WE CHANGE THE DEVICE, THERE'S  
11:10AM 12 SOMETHING STILL GOING ON THAT IS CAUSING ONE OUT OF FOUR  
11:10AM 13 FAILURES OF EVERY SINGLE TEST THAT WE DO ON THIS EDISON SYSTEM,  
11:10AM 14 RIGHT?

11:10AM 15 EVEN IF YOU CHANGE THE DEVICE, IT SEEMS LIKELY THAT MAYBE  
11:10AM 16 THERE'S SOME ISSUE WITH THE CHEMISTRY, MAYBE -- WHATEVER THE  
11:10AM 17 ISSUE MIGHT BE, IT'S STILL THE FACT THAT I KNOW WHEN I RUN FOUR  
11:11AM 18 TESTS, THAT ONE OF THEM IS LIKELY NOT TO WORK BASED ON THE  
11:11AM 19 CUMULATIVE DATA THAT WE'RE RUNNING FOR THE QC ANALYSIS AND  
11:11AM 20 BASICALLY GETTING AN UNDERSTANDING OF HOW MANY FAILURES WE'RE  
11:11AM 21 HAVING FOR QC, AND THIS IS JUST ONE MONTH.

11:11AM 22 BY MR. BOSTIC:

11:11AM 23 Q. UNDERSTOOD. THANK YOU.

11:11AM 24 YOUR HONOR, THIS MIGHT BE A GOOD TIME FOR A BREAK?

11:11AM 25 THE COURT: LET'S DO THAT, LADIES AND GENTLEMEN.

03:19PM

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DATED: MARCH 23, 2022

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
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UNITED STATES OF AMERICA, )  
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 VS. )  
 ) MARCH 30, 2022  
 RAMESH "SUNNY" BALWANI, )  
 ) VOLUME 11  
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 ) PAGES 1444 - 1682

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TRANSCRIPT PRODUCED WITH COMPUTER

10:13AM 1 STANDARD DEVIATION, AND PERCENT CV, OR COEFFICIENT OF

10:13AM 2 VARIATION, FOR EACH ANALYTE ON EACH METHOD.

10:13AM 3 DO YOU SEE THAT?

10:13AM 4 A. YES.

10:13AM 5 Q. AND THEN 4.6 SAYS THE PROCEDURE IS TO CALCULATE THE

10:14AM 6 AVERAGE BIAS OF THE THERANOS LDT TEST AS FOLLOWED AVERAGE BIAS

10:14AM 7 EQUALS MEAN THERANOS MINUS MEAN IMMULITE/MEAN IMMULITE; RIGHT?

10:14AM 8 A. YES.

10:14AM 9 Q. THAT'S LIKE AN EQUATION; RIGHT?

10:14AM 10 A. YES.

10:14AM 11 Q. AND YOU WERE NOT INVOLVED IN DEVISING THOSE EQUATIONS?

10:14AM 12 A. NO.

10:14AM 13 Q. AND THERE WERE OTHER PEOPLE WHO HAD THAT EXPERTISE AT

10:14AM 14 THERANOS WHO WERE DOING THAT?

10:14AM 15 A. CORRECT.

10:14AM 16 Q. AND THEN IF YOU GO TO THE ACCEPTANCE CRITERIA, SECTION 5,

10:14AM 17 THIS SETS OUT WHAT WOULD BE DEEMED TO BE PASSING AND WHAT WOULD

10:14AM 18 NOT BE DEEMED TO BE PASSING; RIGHT?

10:14AM 19 A. CORRECT.

10:14AM 20 Q. SO, FOR EXAMPLE, 5.2 SAYS, "IF AN ANALYTE FAILS MORE THAN

10:14AM 21 20 PERCENT (1 OUT OF 5) OF THE PATIENT CLINICAL SAMPLES, THEN

10:14AM 22 THE PROFICIENCY TESTING WILL BE DEEMED TO HAVE FAILED THE

10:14AM 23 PROFICIENCY EVENT."

10:14AM 24 DO YOU SEE THAT?

10:14AM 25 A. YES.

11:09AM 1 A. NOT ALL OF THE TIME, NO.

11:09AM 2 Q. OKAY. SO, FOR EXAMPLE, IF YOU LOOK AT SECTION 2.8, IT

11:09AM 3 TALKS ABOUT SOMETHING CALLED THE WESTGARD RULES?

11:09AM 4 A. YES.

11:09AM 5 Q. AND DO YOU UNDERSTAND THAT THAT'S A PARTICULAR SET OF

11:09AM 6 RULES INVENTED BY SOMEONE NAMED WESTGARD THAT GOVERN HOW LABS

11:09AM 7 ARE SUPPOSED TO LOOK AT CONTINUOUS QC?

11:09AM 8 A. YES.

11:09AM 9 Q. AND ARE YOU AN EXPERT IN WESTGARD RULES?

11:10AM 10 A. NO.

11:10AM 11 Q. AND WAS IT YOUR JOB TO IMPLEMENT WESTGARD RULES?

11:10AM 12 A. SOMETIMES.

11:10AM 13 Q. SOMETIMES. SO YOU HAD SOME IDEA OF WHAT IT WAS?

11:10AM 14 A. YES.

11:10AM 15 Q. AND IT'S PART OF THE QC PROCESS TO LOOK AT THE DATA IN THE

11:10AM 16 TRENDS; CORRECT?

11:10AM 17 A. YES.

11:10AM 18 Q. AND IF THERE WAS SOME PROBLEM WITH THE WAY THE DATA

11:10AM 19 TRENDS, THAT WOULD ALSO BE A REASON WHY A DEVICE WOULD BE

11:10AM 20 DEEMED TO FAIL QC?

11:10AM 21 A. YES.

11:10AM 22 Q. AND IF YOU GO TO THE NEXT PAGE, DO YOU SEE THAT THERE'S AN

11:10AM 23 EDISON QC SECTION, AND THERE'S AN EDISON DAILY QC; RIGHT?

11:10AM 24 A. CORRECT.

11:10AM 25 Q. AND IF YOU GO TO SECTION 3.2.1 IN PARTICULAR, IT SAYS,

01:16PM 1 Q. DID YOU LEARN MORE ABOUT THE COMPANY'S TESTING OPERATIONS  
01:16PM 2 AND TECHNOLOGY AFTER YOU JOINED THE COMPANY?

01:16PM 3 A. YES.

01:16PM 4 Q. WHEN YOU FIRST JOINED, WHAT DEVICES WAS THERANOS USING TO  
01:16PM 5 CONDUCT ITS PATIENT TESTS?

01:16PM 6 A. THERE WERE MANY. THEY WERE USING FDA CLEARED EQUIPMENT  
01:16PM 7 THAT ANY LAB MIGHT USE, LIKE AN IMMULITE OR A SIEMENS PIECE OF  
01:16PM 8 EQUIPMENT FOR CHEMICAL ANALYSIS. SO THESE WERE THE FDA CLEARED  
01:17PM 9 EQUIPMENT THAT ANY LABORATORY, ANY PARTICULAR CLINICAL  
01:17PM 10 LABORATORY MIGHT PURCHASE AND USE.

01:17PM 11 THEY WERE THEN USING A VERSION OF A SIEMENS ANALYZER THAT  
01:17PM 12 HAD BEEN MODIFIED TO RUN DILUTED SAMPLES.

01:17PM 13 AND THEN THEY WERE USING SOMETHING CALLED EDISONS, WHICH  
01:17PM 14 WERE MACHINES THAT RAN A DIFFERENT CLASS OF BLOOD TEST WHICH WE  
01:17PM 15 REFER TO AS IMMUNOASSAY, AND THOSE WERE BUILT -- THEY WERE  
01:17PM 16 CREATED BY THERANOS.

01:17PM 17 Q. AND SO OF THOSE CATEGORY OF DEVICES THAT YOU JUST LISTED,  
01:17PM 18 WHICH OF THOSE WERE ACTUALLY DESIGNED AND MANUFACTURED BY  
01:17PM 19 THERANOS ITSELF?

01:17PM 20 A. THE EDISONS, TO MY KNOWLEDGE, WERE DESIGNED AND BUILT BY  
01:17PM 21 THERANOS.

01:17PM 22 THE MACHINES -- THEN THERE WAS A VERSION OF THE FDA  
01:17PM 23 CLEARED MACHINE, AND THAT SOME PEOPLE AT THE COMPANY CALLED IT  
01:17PM 24 HACKED, H-A-C-K-E-D, THAT WAS THEIR LANGUAGE, TO RUN -- TO  
01:18PM 25 HANDLE THE LOWER VOLUMES.



01:21PM 1 SIMULTANEOUSLY.

01:21PM 2 AND THEN THE FAILURE RATE OF THE CONTROLS ON THE EDISONS

01:22PM 3 WAS NOTABLY HIGHER THAN WHAT I WOULD SEE ON THE ASSAY EQUIPMENT

01:22PM 4 WITH WHICH I HAD FAMILIARITY, EITHER LITERATURE OR DIRECT USE

01:22PM 5 OR SUPERVISORIAL ROLE OVER.

01:22PM 6 Q. LET ME ASK, AS YOU CAME TO UNDERSTAND THESE THINGS ABOUT

01:22PM 7 THE EDISON DEVICE, WAS THAT CONSISTENT OR INCONSISTENT WITH

01:22PM 8 WHAT YOU HAD READ IN PUBLICLY AVAILABLE INFORMATION AT

01:22PM 9 THERANOS?

01:22PM 10 A. AT THAT TIME IT WAS INCONSISTENT.

01:22PM 11 Q. LET ME TALK A LITTLE BIT MORE ABOUT YOUR ROLE AT THERANOS

01:22PM 12 SPECIFICALLY. I'M SORRY IF YOU SAID ALREADY, BUT WHAT WAS YOUR

01:22PM 13 TITLE THERE?

01:22PM 14 A. LABORATORY DIRECTOR.

01:22PM 15 Q. AND WHAT DID THAT MEAN FOR YOU AT THERANOS? WHAT WAS

01:22PM 16 INCLUDED IN YOUR RESPONSIBILITY?

01:22PM 17 A. FOR ME IT INCLUDED OVERSIGHT OF WHAT WAS CALLED CLIA

01:22PM 18 LABORATORY, AND IT WAS LARGELY AN OPERATIONAL AND LOGISTICS

01:22PM 19 ROLE TO MAKE SURE THAT THINGS WERE BEING TESTED IN A RAPID

01:23PM 20 MANNER, IN A PROPER MANNER, AND THAT I WAS MANAGING THE

01:23PM 21 LABORATORY SCIENTISTS TO MAKE SURE THAT THEY WERE GETTING THEIR

01:23PM 22 JOBS DONE, AND I WAS TO CONSULT WITH ADAM ROSENDORFF WHO WAS

01:23PM 23 ALSO A LABORATORY DIRECTOR.

01:23PM 24 Q. AND YOU MENTIONED DR. ROSENDORFF. CAN YOU TELL US MORE

01:23PM 25 ABOUT HOW YOU FIT INTO THE -- EXCUSE ME -- THE ORGANIZATIONAL

01:32PM 1 THAT SAMPLE OVER AND OVER AGAIN IN THE MACHINE OR THE LAB TEST?

01:32PM 2 A COEFFICIENT OF VARIATION OF 10 IN THAT CASE WOULD BE

01:32PM 3 THAT YOU WOULD GENERALLY SEE VALUES BETWEEN 90 AND 110 IF THE

01:32PM 4 EXPECTED VALUE IS 100.

01:32PM 5 DOES 'THAT' HELP?

01:32PM 6 Q. YES. THANK YOU.

01:32PM 7 A. MORE TECHNICALLY, IT'S THE STANDARD DEVIATION DIVIDED BY

01:32PM 8 THE MEAN.

01:32PM 9 Q. AND AS A LABORATORY DIRECTOR, ARE YOU HOPING TO SEE A

01:32PM 10 LARGE COEFFICIENT OF VARIATION OR A SMALL COEFFICIENT OF

01:32PM 11 VARIATION?

01:32PM 12 A. YOU WANT TESTS TO HAVE SMALL COEFFICIENT OF VARIATIONS.

01:32PM 13 Q. AND CAN YOU EXPLAIN WHY THAT IS?

01:32PM 14 A. WELL, IT'S PLAYS TO THE ACCURACY AND PRECISION OF A TEST.

01:32PM 15 IF A TEST DRIFTS QUITE A BIT AND THE NUMBER IS IMPORTANT FOR

01:32PM 16 MAKING A MEDICAL ACTION BASED ON THE TEST RESULT, YOU NEED THAT

01:32PM 17 NUMBER, YOU NEED TO BE CONFIDENT IN THAT NUMBER.

01:32PM 18 IF THE COEFFICIENT OF VARIATION IS LOW, THEN THAT MEANS

01:33PM 19 THAT YOU CAN FEEL CONFIDENT THAT THE VALUE THAT YOU GET IN THE

01:33PM 20 LAB TEST RESULT IS GOING TO BE VERY CLOSE TO THE TRUE VALUE.

01:33PM 21 Q. DURING YOUR TIME AT THERANOS, DID YOU HAVE OCCASION TO

01:33PM 22 BECOME FAMILIAR WITH HOW THE THERANOS DEVICE -- OF COURSE --

01:33PM 23 HOW THE THERANOS DEVICE PERFORMED IN CONNECTION WITH

01:33PM 24 COEFFICIENT OF VARIATION?

01:33PM 25 A. YOU SAID THERANOS EQUIPMENT?

02:03PM 1 DO YOU SEE THAT?

02:03PM 2 A. I SEE IT.

02:03PM 3 Q. IS THIS THE INFORMATION THAT YOU STARTED TO REFERENCE  
02:03PM 4 EARLIER ABOUT THE OVERALL FAILURE RATE?

02:04PM 5 A. IT IS IN FACT.

02:04PM 6 Q. LET'S FLIP TO THE NEXT PAGE AND ACTUALLY LOOK AT THOSE  
02:04PM 7 NUMBERS.

02:04PM 8 A. I'M THERE.

02:04PM 9 Q. OKAY. GIVE US ONE SECOND TO GET IT ON THE SCREEN.

02:04PM 10 DO YOU REMEMBER GETTING THIS INFORMATION IN MARCH 2014?

02:04PM 11 A. THE EMAIL REFRESHES MY MEMORY IN THAT REGARD.

02:04PM 12 Q. OKAY. AS LAB DIRECTOR AT THAT TIME, WHAT WAS YOUR  
02:04PM 13 REACTION TO SEEING THESE QC FAILURE NUMBERS?

02:04PM 14 A. I WAS DISAPPOINTED, UPSET, CONCERNED BECAUSE THESE ARE  
02:04PM 15 HIGH VALUES FOR A FREQUENCY OF QUALITY CONTROL FAILURE, AND

02:04PM 16 IT'S EMBLEMATIC OF TWO POSSIBLE PROBLEMS FROM A DIAGNOSTIC LAB

02:04PM 17 PERSPECTIVE, SEVERAL, BUT MOST IMPORTANTLY ACCURACY OF THE TEST

02:04PM 18 BEING AN ISSUE, THE RELIABILITY OF THE TEST, BUT ALSO

02:05PM 19 TURNAROUND TIME.

02:05PM 20 SO EVEN IF THE TEST IS SOMEHOW INACCURATE, HAVING TO  
02:05PM 21 CONSTANTLY RERUN QC WOULD MAKE YOU HAVE TO RERUN TESTS.

02:05PM 22 AND THAT TURNAROUND TIME SOUNDS LIKE, WELL, IT'S NOT A BIG  
02:05PM 23 DEAL, IT'S JUST GOING TO TAKE LONGER TO RERUN A LAB TEST.

02:05PM 24 BUT IF YOU HAVE TO RERUN A LAB TEST, SOMETIMES YOU HAVE TO  
02:05PM 25 GO BACK AND DO A REDRAW. SO IF YOU -- YOU'D HAVE TO GET

02:05PM 1 REDRAWN, AND SO THAT HAS IMPACTS FOR THE PATIENT AS WELL.

02:05PM 2 Q. SO YOU'RE DESCRIBING TWO SEPARATE PROBLEMS REALLY: ONE  
02:05PM 3 ABOUT EFFICIENCY AND SLOWING THINGS DOWN, AND ANOTHER ABOUT  
02:05PM 4 ACCURACY PROBLEMS FOR PATIENT TESTS; IS THAT RIGHT?

02:05PM 5 A. CORRECT.

02:05PM 6 Q. YOU SAID THAT YOU WERE, I THINK, DISAPPOINTED BY THESE  
02:05PM 7 NUMBERS.

02:05PM 8 CAN YOU HELP US UNDERSTAND WHY THAT WAS? WHAT NUMBERS  
02:05PM 9 WERE YOU USED TO OR WHAT NUMBERS WERE YOU HOPING TO SEE IN THIS  
02:05PM 10 KIND OF QC TESTING?

02:06PM 11 A. I'M MORE USED TO A RATE OF CONTROL FAILURE BEING -- AND  
02:06PM 12 THEY VARY FROM TEST TO TEST, BUT REALLY BEING MORE THAN IN THE  
02:06PM 13 1 PERCENT OR LESS RANGE.

02:06PM 14 Q. WHEREAS HERE WE SEE THAT SOME ASSAYS WERE FAILING AT A  
02:06PM 15 RATE OF 23 PERCENT, OR 30 PERCENT, OR 45 PERCENT, OR EVEN ABOVE  
02:06PM 16 50 PERCENT; IS THAT RIGHT?

02:06PM 17 A. CORRECT.

02:06PM 18 Q. DOES A QC FAILURE RATE OF 50 PERCENT, OR EVEN 26 PERCENT,  
02:06PM 19 CAUSE YOU CONCERNS AS A LAB DIRECTOR ABOUT THE ACCURACY OF  
02:06PM 20 PATIENT RESULTS?

02:06PM 21 A. WELL, IN THE EXAMPLE WHERE THERE'S A -- WHERE THE CONTROL  
02:06PM 22 IS FAILING 51.3 PERCENT OF THE TIME, THAT MEANS THAT -- THAT'S  
02:06PM 23 LIKE FLIPPING A COIN, SO IF YOU HAVE TAILS, THE MACHINE WORKS,  
02:06PM 24 IF YOU HAVE HEADS, IT DOESN'T.

02:06PM 25 Q. AND IS THAT A FAVORABLE PERCENTAGE FOR A MEDICAL LAB TEST

02:09PM

1

A. I REMEMBER THAT.

02:09PM

2

Q. AND HERE WE SEE AN EXAMPLE OF A SITUATION WHERE IT SAYS  
THAT "EACH READER HAD TWO CONSECUTIVE FAILURES."

02:09PM

3

02:09PM

4

WOULD IT MAKE IT HARDER TO SOLVE THAT PROBLEM USING  
ADDITIONAL READERS?

02:09PM

5

02:09PM

6

A. YES.

02:09PM

7

Q. DURING YOUR TIME AT THERANOS, WAS THERE EVER A SATISFYING  
SOLUTION TO THE PROBLEM OF POOR QC PERFORMANCE ON THE EDISONS?

02:09PM

8

A. THERE WAS NEVER A SOLUTION TO POOR PERFORMANCE, NO.

02:09PM

9

02:09PM

10

Q. AND WERE THOSE PROBLEMS ON YOUR MIND AND PART OF YOUR  
THINKING WHEN YOU DECIDED TO LEAVE THE COMPANY?

02:10PM

11

A. PARTLY -- IT WAS A PART OF MANY THINGS ON MY MIND, YEAH.

02:10PM

12

02:10PM

13

Q. LET'S SHIFT GEARS AND TALK ABOUT PROFICIENCY TESTING.

02:10PM

14

WERE YOU ALSO INVOLVED IN PROFICIENCY TESTING AS LAB  
DIRECTOR AT THERANOS?

02:10PM

15

A. I WAS INVOLVED.

02:10PM

16

Q. AND WHAT WAS YOUR INVOLVEMENT? DESCRIBE THAT?

02:10PM

17

A. WELL, I PAID AN INTEREST IN THE RESULTS OF THEM AND THE  
PERFORMANCE, AND I SOUGHT TO ENSURE THAT IT WAS BEING DONE  
PROPERLY FROM A REGULATORY PERSPECTIVE.

02:10PM

18

02:10PM

19

Q. AND BASED ON WHAT YOU SAW AT THERANOS, DID YOU HAVE  
CONCERNS ABOUT THE COMPANY'S PROFICIENCY TESTING PRACTICES?

02:10PM

22

A. YES.

02:10PM

23

Q. WHAT WERE THOSE CONCERNS?

02:10PM

24

A. WHEN I ARRIVED THERE AND LEARNED INITIALLY THAT PT HAD --

02:10PM

25

02:10PM 1 SHOULD WE EXPLAIN PROFICIENCY TESTING OR --

02:10PM 2 Q. LET'S DO THAT. IF YOU COULD GIVE US AN OVERVIEW OF WHAT

02:10PM 3 THAT IS AND HOW IT'S DONE?

02:10PM 4 A. PROFICIENCY TESTING IS A REGULATORY REQUIREMENT THAT

02:11PM 5 EXISTS FOR LABORATORIES THAT PERFORM DIAGNOSTIC TESTING.

02:11PM 6 IT'S AN EXAM ESSENTIALLY THAT LAB TESTS HAVE TO TAKE TWO

02:11PM 7 OR THREE TIMES A YEAR.

02:11PM 8 SO WHAT HAPPENS IS THAT A THIRD PARTY, A NEUTRAL AGENCY

02:11PM 9 HAS SPECIMENS WHERE THEY KNOW THE ANSWERS TO THOSE SPECIMENS.

02:11PM 10 THEY SEND THEM TO LABS.

02:11PM 11 LABS PERFORM THEIR TESTS ON THOSE SPECIMENS, AND THEN SEND

02:11PM 12 THE RESULTS BACK TO THE AGENCY, AND THE AGENCY GRADES THAT

02:11PM 13 TEST.

02:11PM 14 YOU HAVE TO SCORE 80 PERCENT FOR THAT TEST TO BE

02:11PM 15 CONSIDERED ON LINE. ANYTHING LESS THAN 100 HAS TO BE

02:11PM 16 INVESTIGATED.

02:11PM 17 THE MOST IMPORTANT THING ABOUT PROFICIENCY TESTING IS THAT

02:11PM 18 IT'S A NEUTRAL WAY TO ASCERTAIN THE QUALITY OF YOUR TEST, BUT

02:11PM 19 THAT IT HAS TO BE PERFORMED IN A MANNER THAT IS IDENTICAL TO

02:11PM 20 THE WAY THAT YOU'RE TREATING PATIENT SPECIMENS, OTHERWISE IN A

02:12PM 21 SENSE IT'S LIKE GETTING SOMEONE ELSE TO TAKE THE TEST FOR YOU.

02:12PM 22 Q. SO WITH THAT UNDERSTANDING, WHAT WAS IT ABOUT THERANOS'S

02:12PM 23 PROFICIENCY TESTING PRACTICES THAT CAUSED CONCERNS FOR YOU?

02:12PM 24 A. IT WAS BROUGHT TO MY ATTENTION WHEN I ARRIVED THERE THAT

02:12PM 25 PROFICIENCY TESTING HAD BEEN DONE ON PREDICATE THIRD PARTY --

02:12PM 1 AS YOU REFERRED TO THIRD PARTY EQUIPMENT.

02:12PM 2 Q. AND WHY WAS THAT A PROBLEM?

02:12PM 3 A. BECAUSE SOME SPECIMENS WERE BEING TESTED USING THE  
02:12PM 4 THERANOS METHODS.

02:12PM 5 Q. AND SO YOU'RE DESCRIBING A MISMATCH BETWEEN HOW PATIENT  
02:12PM 6 TESTING WAS CONDUCTED AND HOW THE PROFICIENCY TESTING WAS DONE?

02:12PM 7 A. CORRECT.

02:12PM 8 Q. AND WHY DOES THAT MATTER?

02:12PM 9 A. WELL, THE REGULATIONS ARE VERY CLEAR AT THE FEDERAL LEVEL  
02:12PM 10 AND MOST STATE LEVELS THAT PROFICIENCY TESTING HAS TO BE DONE  
02:12PM 11 IN A MANNER IDENTICAL TO THE WAY THAT PATIENT TESTS ARE  
02:12PM 12 TREATED.

02:12PM 13 IF PATIENTS AT THERANOS, SPECIMENS ARE BEING TESTED ON TWO  
02:13PM 14 DIFFERENT PIECES OF TECHNOLOGY, THEN YOU HAVE TO PERFORM  
02:13PM 15 PROFICIENCY TESTING ON BOTH METHODS.

02:13PM 16 IF YOU'RE PERFORMING THEM ON ONE AND NOT THE OTHER, YOU'RE  
02:13PM 17 NOT DETERMINING THE QUALITY OR PERFORMANCE IN AN OBJECTIVE  
02:13PM 18 MANNER. YOU'RE NOT DETERMINING THE QUALITY OF THE PERFORMANCE  
02:13PM 19 OF THE TEST FOR WHICH PT IS NOT BEING DONE, AND PT IS SHORT FOR  
02:13PM 20 PROFICIENCY TESTING.

02:13PM 21 Q. I SEE.

02:13PM 22 WAS THERE A TIME IN EARLY 2014 WHEN SOME PROFICIENCY  
02:13PM 23 TESTING SAMPLES WERE RUN ON THE EDISON?

02:13PM 24 A. YES.

02:13PM 25 Q. I'LL ASK YOU TO LOOK AT -- LET'S SEE. DO WE HAVE TAB 1524

02:16PM 1 SPECIMENS;

02:16PM 2 AND, SECONDLY, I THOUGHT WE COULD SEE HOW WELL THE  
02:16PM 3 PREDICATE METHODS -- AT LEAST I COULD GET FIRSTHAND DATA ON HOW  
02:16PM 4 WELL THE PREDICATE METHODS MATCHED THE THERANOS METHODS.

02:16PM 5 Q. OKAY. AND WHY WAS THAT IMPORTANT TO SEE, THE MATCH OR  
02:16PM 6 MISMATCH BETWEEN THERANOS METHODS AND THE PREDICATE METHODS YOU  
02:16PM 7 CALLED THEM?

02:16PM 8 A. WE CALLED THEM -- PREDICATE WAS A TERM THAT WE WOULD USE  
02:16PM 9 AT LEAST IN THIS CONTEXT IT WOULD BE AN FDA CLEARED LAB TEST  
02:17PM 10 THAT YOU COULD BUY FROM A COMPANY THAT HAS UNDERGONE CLINICAL  
02:17PM 11 TRIALS AND IS ROUTINELY IN USE IN SEVERAL DIAGNOSTIC  
02:17PM 12 LABORATORIES.

02:17PM 13 Q. OKAY. AND SO WHY WERE YOU INTERESTED IN SEEING THAT  
02:17PM 14 CORRELATION?

02:17PM 15 A. WELL, A PREDICATE METHOD IS -- WOULD HAVE BEEN AN  
02:17PM 16 EXTRAORDINARILY VETTED METHODOLOGY OF LAB TESTING.

02:17PM 17 THAT IS TO SAY A PREDICATE METHOD WILL HAVE UNDERGONE  
02:17PM 18 CLINICAL TRIAL, WHICH ACCORDING TO THE UNITED STATES  
02:17PM 19 REGULATIONS IS A MASSIVE AMOUNT OF OBSERVATION AND ASSESSMENT.

02:17PM 20 SO ONE MIGHT FEEL VERY CONFIDENT THAT A PREDICATE METHOD  
02:17PM 21 WILL GIVE AN ACCURATE RESULT ON A PATIENT, AND SO I WANTED TO  
02:17PM 22 SEE FOR MYSELF WHAT WOULD HAPPEN IF WE COMPARED IT TO A  
02:17PM 23 THERANOS METHOD.

02:17PM 24 Q. OKAY. LOOKING AT THE DATA THAT RESULTED FOR THE FOUR  
02:17PM 25 ASSAYS THAT WERE TESTED -- I GUESS LET ME JUST ASK, DID YOUR



02:18PM 1 WISH COME TRUE? DID YOU SEE DATA WHERE THERANOS MATCHED THE  
02:18PM 2 PREDICATE TESTING CLOSELY?

02:18PM 3 A. THERE'S QUITE A LOT OF DIFFERENCE IN THESE RESULTS. YOU  
02:18PM 4 WOULD NEED TO BE, YOU KNOW, AN EXPERT TO APPRECIATE THE  
02:18PM 5 DIFFERENCES BECAUSE THOSE DIFFERENCES DON'T LOOK LARGE BUT  
02:18PM 6 THERE'S LARGE DIFFERENCES THERE.

02:18PM 7 WITH REGARD TO VITAMIN D, THERE'S PARTICULARLY LARGE  
02:18PM 8 DIFFERENCES FOR THAT.

02:18PM 9 Q. AND --

02:18PM 10 A. BUT FOR THESE OTHER TESTS, THERE ARE DIFFERENCES OF NOTE.

02:18PM 11 Q. I APOLOGIZE FOR TALKING OVER YOU.

02:18PM 12 FOR VITAMIN D YOU'RE REFERRING TO THE TOP FEW ROWS OF THE  
02:18PM 13 CHART?

02:18PM 14 A. I'M REFERRING TO ROWS 2, 3, 4, AND COLUMNS A THROUGH G.

02:18PM 15 Q. OKAY. AND ARE YOU REFERENCING THE DIFFERENCES BETWEEN THE  
02:18PM 16 THERANOS RESULTS AS COMPARED TO THE PREDICATE FDA APPROVED  
02:19PM 17 RESULTS?

02:19PM 18 A. I AM.

02:19PM 19 Q. OKAY. GENERALLY SPEAKING, WERE YOU HAPPY WITH THESE  
02:19PM 20 RESULTS WHEN THEY CAME IN IN FEBRUARY OF 2014?

02:19PM 21 A. NO, I WAS NOT HAPPY WITH THESE RESULTS.

02:19PM 22 Q. DID THEY CAUSE YOU TO HAVE CONCERNS ABOUT THE ACCURACY OF  
02:19PM 23 THERANOS'S TESTING?

02:19PM 24 A. YEAH, I HAD -- THESE CAUSED ME TO HAVE CONCERNS ABOUT THE  
02:19PM 25 ACCURACY.

02:19PM 1 YOU KNOW, FOR VITAMIN D, THIS IS A TEST THAT GENERALLY IS  
02:19PM 2 A COEFFICIENT OF VARIATION FOR -- IF YOU LOOK AT PREDICATE  
02:19PM 3 METHODS OUT THERE, IT WOULD BE A TEST THAT WOULD HAVE A  
02:19PM 4 COEFFICIENT OF VARIATION OF PROBABLY 10 PERCENT, AND THIS IS  
02:19PM 5 WAY BEYOND 'THAT'.

02:19PM 6 Q. LOOKING AT SOME OF THE TPSA RESULTS, DO YOU SEE THAT THERE  
02:19PM 7 WERE TWO SAMPLES THAT WERE RUN TWICE?

02:19PM 8 A. YEP.

02:19PM 9 Q. AND THESE RERUNS ARE MARKED IN RED; IS THAT RIGHT?

02:19PM 10 A. YES.

02:19PM 11 Q. WHAT, IF ANYTHING, DO YOU DRAW FROM THE PERFORMANCE OF THE  
02:20PM 12 PREDICATE METHOD VERSUS THE THERANOS METHOD IN THOSE CASES  
02:20PM 13 WHERE THE SAMPLES ARE RUN TWICE?

02:20PM 14 A. THIS IMPLIES POOR PRECISION, WHICH IS A LABORATORY,  
02:20PM 15 QUALITY LABORATORY TERM WHICH APPLIES TO REPEATABILITY.

02:20PM 16 IF YOU THINK OF A DARTBOARD, ACCURACY WOULD BE HOW OFTEN I  
02:20PM 17 HIT THE BULL'S EYE.

02:20PM 18 PRECISION WOULD BE HOW OFTEN CAN I -- HOW WELL DO I  
02:20PM 19 CLUSTER MY DARTS.

02:20PM 20 SO AN ACCURATE AND PRECISE TEST WOULD BE ALL OF MY DARTS  
02:20PM 21 IN THE BULL'S EYE.

02:20PM 22 A PRECISE TEST BUT AN INACCURATE TEST WOULD BE THAT ALL OF  
02:20PM 23 MY DARTS ARE CLUSTERED ON THE DARTBOARD, BUT THEY'RE NOT ON THE  
02:20PM 24 BULL'S EYE.

02:20PM 25 SO YOU CAN HAVE PRECISION WITHOUT ACCURACY.

02:20PM 1 WHAT I'M SEEING HERE IS THAT THE PREDICATE METHOD WAS  
02:20PM 2 PRECISE. IT GAVE THE EXACT SAME RESULT ON BOTH OCCASIONS  
02:20PM 3 WHEREAS THE THERANOS METHOD GAVE DRASTICALLY, CONSIDERABLY  
02:20PM 4 DIFFERENT RESULTS ON BOTH OCCASIONS.  
02:21PM 5 Q. AND DOES SOMETHING LIKE THAT CAUSE CONCERNS ABOUT THE  
02:21PM 6 ACCURACY OF PATIENT TESTING?  
02:21PM 7 A. IN THIS CASE BOTH ACCURACY AND PRECISION ARE CALLED INTO  
02:21PM 8 QUESTION.  
02:21PM 9 Q. WHEN THIS TESTING WAS CONDUCTED, WERE YOU FAMILIAR WITH A  
02:21PM 10 TERM CALLED AAP, OR ALTERNATIVE ASSESSMENT PROFICIENCY?  
02:21PM 11 A. YES.  
02:21PM 12 Q. AND WERE YOU GENERALLY FAMILIAR WITH WHAT THE REGULATIONS  
02:21PM 13 SAY ABOUT PROFICIENCY TESTING AND AAP?  
02:21PM 14 A. YES.  
02:21PM 15 Q. AND HOW ABOUT THE INTERNAL THERANOS SOP'S ON PROFICIENCY  
02:21PM 16 TESTING, WERE YOU GENERALLY FAMILIAR WITH THOSE?  
02:21PM 17 A. NO.  
02:21PM 18 Q. OKAY. AS LABORATORY DIRECTOR AT THERANOS, WAS THERE A  
02:21PM 19 REASON WHY FAMILIARITY WITH INTERNAL SOP'S WASN'T NECESSARY TO  
02:22PM 20 YOUR SOP OR WHY IT HADN'T COME UP?  
02:22PM 21 A. THE SOP FOR PERFORMING PROFICIENCY TESTING, YOUR QUESTION  
02:22PM 22 IS WHY -- I'M JUST NOT SURE I UNDERSTAND.  
02:22PM 23 Q. SURE.  
02:22PM 24 WAS THE CONTENT OF THAT SOP RELEVANT TO THE WORK THAT YOU  
02:22PM 25 WERE DOING AT THE COMPANY?

02:30PM 1 FORMAL SCIENTIFIC EDUCATION?

02:30PM 2 A. CAN YOU RESTATE.

02:30PM 3 Q. SURE.

02:30PM 4 THE KIND OF WORK THAT HE'S OFFERING TO DO HERE OR

02:30PM 5 DEMANDING TO DO, REVIEWING THE RAW DATA TO MAKE SURE THE

02:30PM 6 CALIBRATIONS WERE APPLIED, IS THAT THE KIND OF WORK THAT WOULD

02:30PM 7 TYPICALLY BE DONE BY SOMEONE WITH SOME TRAINING IN THE

02:30PM 8 BIOSCIENCES?

02:30PM 9 A. I WOULD THINK THAT IT WOULD BE DONE BY SOMEBODY WHO HAS

02:30PM 10 EXPERIENCE IN DIAGNOSTIC LAB TESTING, MAYBE ANY KIND OF --

02:30PM 11 MAYBE TO SOME DEGREE BIOSTATISTICS BUT EXPERIENCE IN LAB

02:30PM 12 TESTING IS HOW I WOULD HAVE THOUGHT THAT.

02:30PM 13 AND THEN I REMEMBER THINKING READING THIS, OH, MAYBE HE'LL

02:30PM 14 HAVE SOMEONE ELSE TAKE A LOOK AT IT.

02:31PM 15 Q. OKAY. LET'S MOVE UP THROUGH THIS CHAIN AND LOOK AT

02:31PM 16 ANOTHER REACTION BY MR. BALWANI ON PAGE 3.

02:31PM 17 AND ON PAGE 3, LET'S ZOOM IN ON THE MIDDLE OF THE PAGE.

02:31PM 18 MR. BALWANI SAYS, "OUR VALIDATION AGAINST IMMULITE HAS BEEN

02:31PM 19 EXCELLENT IN THE PAST. IT IS THESE PT SAMPLES THAT ARE OFF."

02:31PM 20 DO YOU SEE THAT?

02:31PM 21 A. I SEE THAT.

02:31PM 22 Q. WHAT IS YOUR UNDERSTANDING OF WHAT HE'S SAYING IN THIS

02:31PM 23 EMAIL?

02:31PM 24 A. WHAT SUNNY IS SAYING IN THIS EMAIL IS THAT A VALIDATION IS

02:31PM 25 A STUDY WHERE YOU'RE TAKING TWO METHODS AND COMPARING THEM TO

02:33PM 1 HE SAYS, "READING THROUGH THE REGULATIONS MORE FINELY --  
02:33PM 2 IF WE DID ENROLL IN PT FOR THERANOS METHODS, WE WOULD NEED TO  
02:33PM 3 DO AN ALTERNATE ASSESSMENT PROTOCOL (AAP) IN ANY EVENT."

02:33PM 4 DO YOU SEE THAT?

02:33PM 5 A. YES.

02:33PM 6 Q. AND IS THIS WHAT WE WERE DISCUSSING AAP VERSUS STANDARD  
02:33PM 7 PROFICIENCY TESTING?

02:33PM 8 A. YES.

02:33PM 9 Q. DR. ROSENDORFF THEN ASKS AT THE BOTTOM OF HIS EMAIL, "MY  
02:33PM 10 QUESTION IS WHAT PT DO WE REPORT TO COMMERCIAL PT PROVIDERS AND  
02:33PM 11 HENCE TO CMS?"

02:33PM 12 DO YOU SEE THAT?

02:33PM 13 A. YES, I SEE IT.

02:33PM 14 Q. WAS THAT YOUR CONCERN, TOO, AT THE TIME, WHAT DATA WAS  
02:33PM 15 BEING REPORTED TO REGULATORS?

02:33PM 16 A. IT WAS MY PRIMARY.

02:34PM 17 Q. LET'S LOOK AT YOUR EMAIL AT THE TOP OF PAGE 1.

02:34PM 18 YOU WRITE BACK TO DR. ROSENDORFF, INCLUDING MR. BALWANI  
02:34PM 19 AND MS. HOLMES.

02:34PM 20 YOU SAY, "ADAM,

02:34PM 21 "SEEMS THAT THE THING TO DO WOULD BE TO REPORT THE  
02:34PM 22 THERANOS METHODS, AS THEY ARE OUR PRIMARY METHODS.

02:34PM 23 "THIS WOULD KEEP US IN FULL COMPLIANCE OF THE REGS, AND  
02:34PM 24 THE LACK OF A PEER GROUP WOULD TRIGGER AN UNGRADED SCORE WHICH  
02:34PM 25 WOULD ALLOW US TO EVALUATE OUR PERFORMANCE."

02:34PM 1 WHY WERE YOU ADVOCATING TO REPORT THE THERANOS METHODS,  
02:34PM 2 THE PRIMARY METHODS, TO THE REGULATORS?  
02:34PM 3 A. THEY WERE BEING USED TO RUN A LARGE NUMBER OF THERANOS  
02:34PM 4 SPECIMENS.  
02:34PM 5 Q. OKAY. LET'S LOOK AT TAB 1580, PLEASE, IN YOUR BINDER.  
02:35PM 6 AND DO YOU SEE THAT 1580 IS A CONTINUATION OF THAT SAME  
02:35PM 7 EMAIL CHAIN?  
02:35PM 8 A. I DON'T -- OH, SORRY.  
02:35PM 9 Q. IN YOUR BINDER.  
02:35PM 10 A. WHAT?  
02:35PM 11 Q. IT'S JUST THE NEXT TAB IN YOUR BINDER, 1580?  
02:35PM 12 A. I WAS LOOKING AT THE SCREEN.  
02:35PM 13 Q. NO PROBLEM?  
02:35PM 14 A. YEAH, I'M THERE.  
02:35PM 15 Q. OKAY. DO YOU SEE THAT THIS IS A CONTINUATION OF THE SAME  
02:35PM 16 EMAIL CHAIN THAT WE WERE JUST LOOKING AT?  
02:35PM 17 A. YES.  
02:35PM 18 Q. AND DO YOU SEE THAT IT CONTINUES TO INCLUDE MR. BALWANI  
02:35PM 19 AND MS. HOLMES?  
02:35PM 20 A. YES.  
02:35PM 21 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1580.  
02:35PM 22 MR. CAZARES: NO OBJECTION.  
02:35PM 23 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.  
02:35PM 24 (GOVERNMENT'S EXHIBIT 1580 WAS RECEIVED IN EVIDENCE.)  
02:35PM 25 BY MR. BOSTIC:

02:35PM 1 Q. LET'S START AT THE BOTTOM HALF OF THE PAGE.

02:35PM 2 FIRST, DO YOU SEE, DR. PANDORI, THE EMAIL FROM

02:35PM 3 ADAM ROSENDORFF REGARDING AAP?

02:36PM 4 A. YES.

02:36PM 5 Q. OKAY. AND THEN MS. HOLMES'S RESPONSE TO THAT; CORRECT?

02:36PM 6 A. YES.

02:36PM 7 Q. AND THEN SHE WRITES, "WE ENGAGED TOP COUNSEL ON THIS SOME

02:36PM 8 TIME AGO. SUNNY WILL DEBRIEF YOU TOMORROW -- IT IS CRITICAL

02:36PM 9 THAT NO ONE IS GUESSING ON MATTERS LIKE THESE."

02:36PM 10 DO YOU SEE THAT?

02:36PM 11 A. YES.

02:36PM 12 Q. AND IN EXPRESSING THE VIEWS THAT YOU AND DR. ROSENDORFF

02:36PM 13 WERE EXPRESSING, WERE YOU GUESSING ABOUT THE REQUIREMENTS?

02:36PM 14 A. NO.

02:36PM 15 Q. WAS IT PART OF YOUR JOB TO UNDERSTAND HOW TO PROPERLY

02:36PM 16 CONDUCT PROFICIENCY TESTING AT A LAB LIKE THIS?

02:36PM 17 A. IT'S PART OF MY JOB AS A LABORATORY DIRECTOR AND IT'S PART

02:36PM 18 OF DR. ROSENDORFF'S JOB AS A LABORATORY DIRECTOR, AND IT'S A

02:36PM 19 NATURAL AND NORMAL THING DONE IN ALL DIAGNOSTIC LABORATORIES.

02:36PM 20 Q. LET'S GO UP TO MR. BALWANI'S RESPONSE AT THE TOP OF

02:36PM 21 PAGE 1.

02:37PM 22 AND LET'S DIVIDE THIS UP SO WE CAN ZOOM IN A LITTLE BIT

02:37PM 23 MORE ACTUALLY. LET'S TAKE THE FIRST HALF FIRST. THANK YOU.

02:37PM 24 YOU SEE THAT MR. BALWANI WRITES IN THAT TOP LINE, "I AM

02:37PM 25 EXTREMELY IRRITATED AND FRUSTRATED BY FOLKS WITH NO LEGAL

02:37PM 1 BACKGROUND TAKING LEGAL POSITIONS AND INTERPRETATIONS ON THESE  
02:37PM 2 MATTERS AND JUNIOR CLIA AND NON-CLIA PERSONNEL CHALLENGING OUR  
02:37PM 3 CLIA SOP'S."

02:37PM 4 DO YOU SEE THAT?

02:37PM 5 A. YES.

02:37PM 6 Q. IN YOUR VIEW AS LABORATORY DIRECTOR AT THIS TIME, WAS  
02:37PM 7 COMPLIANCE WITH PROFICIENCY TESTING JUST A LEGAL REQUIREMENT?

02:37PM 8 A. COMPLIANCE WITH PT TESTING SERVES A REGULATORY  
02:37PM 9 REQUIREMENT, BUT IT REALLY IS -- YOU CAN LOOK AT IT THAT WAY,  
02:37PM 10 BUT PERFORMING PT PROPERLY IS ESSENTIAL FOR AN OBJECTIVE MANNER  
02:38PM 11 IN ASSESSING THE QUALITY AND ACCURACY OF YOUR LAB TESTS, AND  
02:38PM 12 THAT SERVES A PATIENT SAFETY FUNCTION, WHICH IS IN MY MIND MORE  
02:38PM 13 IMPORTANT THAN THE REGULATIONS, BUT PROBABLY WHY REGULATIONS  
02:38PM 14 EXIST OF COURSE.

02:38PM 15 Q. AND IS THAT ASPECT OF IT, THE PATIENT SAFETY ASPECT,  
02:38PM 16 SOMETHING THAT YOU WERE CONCERNED WITH AS LABORATORY DIRECTOR?

02:38PM 17 A. YES.

02:38PM 18 Q. IN THE SECOND PARAGRAPH OF MR. BALWANI'S EMAIL HE SAYS,  
02:38PM 19 "THESE PAST FEW DAYS, WE HAVE WASTED SO MUCH TIME TALKING TO  
02:38PM 20 PEOPLE OUTSIDE OF CLIA WHO HAVE COME TO US TO SHARE THAT OUR PT  
02:38PM 21 ON VITAMIN D ON EDISON HAS FAILED. THESE PT SAMPLES SHOULD  
02:38PM 22 HAVE NEVER RUN ON EDISONS TO BEGIN WITH."

02:38PM 23 DO YOU SEE THAT?

02:38PM 24 A. YES.

02:38PM 25 Q. YOU TESTIFIED EARLIER THAT IT HAD BEEN YOUR DECISION TO



02:38PM 1 RUN THESE SAMPLES ON THE EDISONS?

02:38PM 2 A. YES.

02:38PM 3 Q. DID YOU AGREE WITH MR. BALWANI THAT THAT WAS A MISTAKE?

02:38PM 4 A. I DID NOT AGREE WITH MR. BALWANI THAT THAT WAS A MISTAKE.

02:38PM 5 Q. AND WHY DID YOU DISAGREE?

02:39PM 6 A. BECAUSE IT IS ESSENTIAL BY WAY OF REGULATIONS THAT PT'S

02:39PM 7 ARE TREATED THE SAME WAY THAT PATIENT SPECIMENS ARE TREATED,

02:39PM 8 OTHERWISE YOU'RE NOT TRULY DETERMINING THE QUALITY OF YOUR

02:39PM 9 PROCESS AND YOU'RE NOT HAVING AN OBJECTIVE AND PROPER

02:39PM 10 ASSESSMENT OF THE TEST.

02:39PM 11 Q. LET'S ZOOM OUT AND GO IN ON THE BOTTOM TWO PARAGRAPHS OF

02:39PM 12 MR. BALWANI'S RESPONSE.

02:39PM 13 AND IN THAT BOTTOM PARAGRAPH YOU SEE THAT HE SAYS IN THE

02:39PM 14 MIDDLE, "NO PERSONAL OPINIONS. RIGHT NOW, EVERY CLS OR TS OR

02:39PM 15 GS CONSIDERS THEMSELVES AS REGULATORY EXPERT," AND THEN HE

02:39PM 16 UNDER LINES, "AND THIS CULTURE MUST BE NIP IN THE BUD."

02:39PM 17 DO YOU SEE THAT?

02:39PM 18 A. YEAH, I SEE THAT.

02:39PM 19 Q. FIRST OF ALL, AS LABORATORY DIRECTOR AT THE TIME, DID YOU

02:39PM 20 FEEL QUALIFIED TO GIVE YOUR INPUT ON WHAT PROFICIENCY TESTING

02:40PM 21 SHOULD LOOK LIKE AT THE LAB?

02:40PM 22 MR. CAZARES: OBJECTION. IT CALLS FOR LEGAL

02:40PM 23 CONCLUSION TESTIMONY.

02:40PM 24 THE COURT: ARE YOU ASKING HIM HIS KNOWLEDGE OF THE

02:40PM 25 SCOPE OF HIS EMPLOYMENT?

02:40PM 1 MR. BOSTIC: EXACTLY, YOUR HONOR. I'M HAPPY TO

02:40PM 2 REPHRASE THAT.

02:40PM 3 THE COURT: WHY DON'T YOU. THANK YOU.

02:40PM 4 BY MR. BOSTIC:

02:40PM 5 Q. DR. PANDORI, BASED ON YOUR UNDERSTANDING OF YOUR JOB

02:40PM 6 RESPONSIBILITIES AND THE SCOPE OF YOUR EMPLOYMENT, WAS IT PART

02:40PM 7 OF YOUR RESPONSIBILITY TO GIVE YOUR OPINION AND INPUT ON HOW

02:40PM 8 PROFICIENCY TESTING WAS RUN AT THERANOS?

02:40PM 9 MR. CAZARES: 702.

02:40PM 10 THE COURT: OVERRULED.

02:40PM 11 THE WITNESS: I WASN'T NEVER -- I WASN'T ENTIRELY

02:40PM 12 CLEAR. I DIDN'T HAVE A LIST OF JOB DESCRIPTIONS AND THAT, SO I

02:40PM 13 TOOK IT UPON MYSELF TO MAKE SURE THAT THE LAB WAS RUNNING

02:40PM 14 PROPERLY IN ANY WAY THAT I COULD.

02:40PM 15 AND BECAUSE I HAD A LOT OF EXPERIENCE IN DIRECTING

02:40PM 16 LABORATORY ACTIVITIES AND LOOKING AT PT'S AND I'M BOARD

02:40PM 17 CERTIFIED AS A HIGH COMPLEXITY LABORATORY DIRECTOR, I FELT THAT

02:41PM 18 I COULD CONTRIBUTE IN A MEANINGFUL WAY TO THIS CONVERSATION.

02:41PM 19 BY MR. BOSTIC:

02:41PM 20 Q. YOU LEFT THERANOS IN MAY 2014; IS THAT RIGHT?

02:41PM 21 A. CORRECT.

02:41PM 22 Q. DURING YOUR TIME AT THE COMPANY, DID THERANOS EVER PERFORM

02:41PM 23 PROFICIENCY TESTING IN A WAY THAT SATISFIED YOU?

02:41PM 24 A. I DON'T RECALL I LEFT SO SOON.

02:41PM 25 Q. WAS THERANOS'S APPROACH TO PROFICIENCY TESTING PART OF THE

02:41PM 1 REASONS WHY YOU LEFT THE COMPANY?

02:41PM 2 A. IT WAS PART.

02:41PM 3 Q. THE PROBLEMS YOU SAW AT THERANOS, WERE THEY LIMITED TO THE  
02:41PM 4 EDISON DEVICE OR DID YOU ALSO SEE PROBLEMS WITH THE THERANOS  
02:41PM 5 MODIFIED THIRD PARTY DEVICES?

02:41PM 6 A. THERE WERE PROBLEMS WITH THE HACKED EQUIPMENT AS WELL.

02:42PM 7 Q. WHAT PROBLEMS DID YOU SEE WITH THOSE ITEMS?

02:42PM 8 A. WELL, THEY WERE -- THEY HAD QUALITY CONTROL ISSUES AS I  
02:42PM 9 RECALL, BUT THEY ALSO -- I HAD HEARD THAT THEY HAD GIVEN A  
02:42PM 10 NUMBER OF RESULTS THAT LED ME TO BELIEVE THAT THEY WERE  
02:42PM 11 GENERATING UNRELIABLE RESULTS.

02:42PM 12 Q. IF I COULD ASK YOU TO TURN TO TAB 1562 IN YOUR BINDER,  
02:42PM 13 PLEASE.

02:42PM 14 MR. CAZARES: I'M SORRY, WHAT NUMBER, COUNSEL?

02:42PM 15 MR. BOSTIC: 1562.

02:42PM 16 THE WITNESS: YES.

02:42PM 17 BY MR. BOSTIC:

02:42PM 18 Q. AND AT 1562, DO YOU SEE AN EMAIL CHAIN BETWEEN YOU AND  
02:42PM 19 DR. ROSENDORFF RELATING TO AN EVALUATION OF MODIFIED ANALYZERS  
02:42PM 20 AT THERANOS?

02:42PM 21 A. YES.

02:43PM 22 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1562.

02:43PM 23 MR. CAZARES: ONE MOMENT, YOUR HONOR.

02:43PM 24 (PAUSE IN PROCEEDINGS.)

02:43PM 25 MR. CAZARES: NO OBJECTION.

02:46PM 1 A. I SEE THAT.

02:46PM 2 Q. AND DR. ROSENDORFF RESPONDS, "FOR SURE THE INSTRUMENT BIAS  
02:46PM 3 IS EXACERBATED WITH THE P-PROTOCOLS."

02:46PM 4 CAN YOU EXPLAIN FOR US WHAT THAT MEANS?

02:46PM 5 A. YEAH. HE'S SAYING THAT IN A SENSE THERE'S A CHANCE FOR A  
02:46PM 6 MUCH HIGHER INACCURACY IF YOU'RE RUNNING THE DELETED P PROTOCOL  
02:46PM 7 COMPARED TO THE PREDICATE MACHINE, I MEAN THE PREDICATE METHOD,  
02:46PM 8 SORRY.

02:46PM 9 AND THAT WITH P PROTOCOLS THAT THERE'S SOMETHING ABOUT --  
02:47PM 10 THERE'S A FUNCTION ASPECT TO THE INSTRUMENT THAT IF YOU TRY TO  
02:47PM 11 RUN THESE DILUTED SPECIMENS ON IT, IT DOESN'T WORK AS WELL,  
02:47PM 12 JUST TO BE SORT OF PLAIN ABOUT IT.

02:47PM 13 Q. AND THE TERM "INSTRUMENT BIAS," CAN YOU GIVE US A QUICK  
02:47PM 14 DEFINITION OF WHAT THAT IS REFERRING TO?

02:47PM 15 A. SO THAT THE INSTRUMENT MIGHT INTRODUCE SOME CHANGE OR  
02:47PM 16 VARIATION IN A COUNT OR A MEASUREMENT, AND THAT THAT VARIATION  
02:47PM 17 OR THAT AMOUNT OF CHANGE TO THE RESULT, OR MEASUREMENT I SHOULD  
02:47PM 18 SAY, IS SOMEHOW EXACERBATED OR MADE MORE SERIOUS WHEN YOU RUN  
02:47PM 19 THE P SPECIMENS AND THE P PROTOCOL SPECIMENS.

02:47PM 20 Q. IN OTHER WORDS, DID THE THERANOS MODIFIED VERSIONS OF  
02:47PM 21 THESE DEVICES WORK WORSE THAN THE UNMODIFIED VERSIONS?

02:47PM 22 A. CAN YOU RESTATE THAT?

02:47PM 23 Q. SURE. DID THE THERANOS MODIFIED ANALYZERS WORK WORSE THAN  
02:48PM 24 THE UNMODIFIED VERSIONS?

02:48PM 25 MR. CAZARES: OBJECTION. LEADING.

CERTIFICATE OF REPORTER

I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY CERTIFY:

THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

A handwritten signature in black ink that reads "Irene Rodriguez". The signature is written in a cursive, flowing style with a large, decorative flourish at the end of the last name.

IRENE RODRIGUEZ, CSR, RMR, CRR  
CERTIFICATE NUMBER 8074

DATED: MARCH 30, 2022

## **Exhibit 2**



## UNITED STATES POSTAL INSPECTION SERVICE

### MEMORANDUM OF INTERVIEW

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CASE NUMBER : 2204323-MF

PERSON INTERVIEWED : Dr. Mark Pandori

PLACE OF INTERVIEW : United States Attorney's Office, San Jose, CA

DATE OF INTERVIEW : March 22, 2022

TIME OF INTERVIEW : 5:20 P.M.

INTERVIEWED BY : Assistant United States Attorney John Bostic

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On March 22, 2022, Dr. Mark Pandori (PANDORI) was interviewed at the San Jose office of the United States Attorney in preparation for potential trial testimony. David Pandori, PANDORI's brother, was present as his counsel. The following is a summary of the statements made during the interview. This report may not document all statements made during the interview which have been memorialized in previous memoranda.

PANDORI testified in a deposition related to a Theranos civil matter. He has not testified in any other civil or criminal proceedings.

PANDORI was employed at Theranos from mid-December 2013 until May 2014 when he resigned. He left the company because he felt Theranos' technology was not fully developed nor did it function properly; misrepresentations were made by Theranos sales representatives and Theranos upper management, about the capabilities of Theranos' technology; laboratory personnel were not allowed to use their training and experience to properly troubleshoot lab matters; and lab personnel's professional opinions were disregarded by Sunny Balwani (BALWANI) and Elizabeth Holmes (HOLMES).

PANDORI said misrepresentations about Theranos' ability to run diagnostic testing from small samples were made to physicians and discussed in at least one distinct telephone call he attended with Theranos sales representatives and product managers. HOLMES also misrepresented the technology in multiple published news articles. These misrepresentations were not supported by reality. PANDORI said Theranos VIPs were mislead about how their blood samples were processed. While not present for VIP meetings, PANDORI inferred from his conversations with product managers about the timeliness of the results that these VIPs believed their samples would be run on devices different than how they were actually run. PANDORI had no direct contact with VIPs.

The Edison device ran only one assay at a time.



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PANDORI said Max Fosque (FOSQUE) and Nick Menschell (MENSCHELL) referred to the modified third-party devices as "hacked."

PANDORI reviewed trial exhibit 1491 and said a QC failure prevented a certain assay discussed in the document from being run. The Immulite was a third-party analyzer, but PANDORI could not remember what assays were run on it. PANDORI never saw any blood testing devices outside of the testing area.

PANDORI reviewed trial exhibit 1522 and said HOLMES and BALWANI wanted samples from VIPs different than normal patient samples, namely that they are run first and done more quickly than other samples. PANDORI remembered one specific instance where a result received extra scrutiny from Daniel Young's (YOUNG) group where the results were "massaged."

PANDORI reviewed trial exhibit 1528. PANDORI stated in the document, "I guess my growing concern is why these fail so often." QC for the Theranos devices failed very often, more than in his prior experience. He discussed these issues with ROSENDORFF who never disagreed with PANDORI's assessment. There was a possibility of a cartridge manufacturing issue, but there was no data to prove or disprove that hypothesis. There were three components of blood testing that needed to be examined when issues arose: human, machine, and reagents. PANDORI never saw a convincing solution to the observed problems.

PANDORI reviewed trial exhibit 1595 and said that because quality control failed so often, he developed a temporary plan to identify functional devices for use in the lab with the goal of improving the turnaround-time. This was not a cure all plan and it was not ideal to run one specimen on two devices at a time. PANDORI was concerned that Theranos might have run samples on a device that functioned for QC, but otherwise were not functional.

PANDORI reviewed trial exhibit 1633 and said a 26% failure rate of Edison assays was not acceptable. Ideally, a lab would hope for an overall failure rate of less than one percent. Failure rates of greater than 50% indicated a test was very unreliable for patient testing. These failure rates in March 2014 were typical of PANDORI's time at the company.

PANDORI reviewed trial exhibit 5771 and said it was his idea to run proficiency testing samples on the Edison devices. Regulation required proficiency testing samples be run on the methods used for patient testing. This was not done at Theranos as the company ran proficiency testing using the unmodified methods not reflective of patient testing. Theranos mislead CMS and the proficiency testing organizations. It was not PANDORI's decision to run proficiency testing in the way it was done at Theranos, and ROSENDORFF agreed with PANDORI's assessment. Certified labs can be shutdown for running proficiency testing incorrectly or dishonestly.